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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,436	02/18/2004	Pramod B. Mahajan	1121D	6402

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EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,436	MAHAJAN, PRAMOD B.	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5* is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5 are pending and are examined.

Priority

This application is a divisional of the US application No. 09/589, 510, filed 06/07/2000, now US PAT 6, 706, 949, which claims benefit of 60/1444, 112 filed 07/16/1999. This application is not a continuation of 09/589, 510 as indicated in the specification on page 1, 1st full paragraph and in the application data sheet. Appropriate correction is required.

ABSTRACT

The Abstract on page 73 of the specification has been replaced with the following:

------The invention provides isolated RuvB polypeptides and polynucleotides encoding said polypeptides-------.

Specification

The disclosure is objected to because of the following informalities: for example, page 19, line 27, and page 69, line 18, contain an embedded hyperlink directed to an Internet address. The use of hyperlinks and/or other form of browser- executable code are not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polypeptide of SEQ ID NO: 4, does not reasonably provide enablement for any isolated polypeptide having at least 80%, 85%, and 90% sequence identity to SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant broadly claims any isolated polypeptide comprising an amino acid having at least 80%, 85%, or 90% sequence identity to SEQ ID NO: 4, wherein the polypeptide retains RuvB activity. The scope of the claims encompass large number of polypeptides with a multiple amino acid modifications.

Applicant teaches the isolated polypeptide of SEQ ID NO: 4 from maize, and few other polypeptides also from maize. Applicant has not provided guidance for any modifications to SEQ ID NO: 4 that resulted in a polypeptide having at least 80%, 85%, or 90% sequence identity to SEQ ID NO: 4 and that retains RuvB activity. Applicant has not taught regions in the full-length sequence of SEQ ID NO: 4 that would tolerate multiple amino acid deletions, additions or substitutions. While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple

substitutions, additions and deletions, as encompassed by the instant claims, and the regions within the a proteins' sequence where amino acid mutations can be made with a reasonable expectation of success in obtaining the desired function are limited in any protein and the results of such mutations are unpredictable.

Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires substantial guidance with respect to which amino acids in the protein's sequence, if any, would tolerate to modification, and detailed knowledge of the ways in which protein's structure relates to its function. In addition, making "conservative" substitutions does not usually produce predictable results. See, for example Lazar et al (Mol. Cell. Biol., Vol. 8, pp. 1247-1252, 1988(U)) who teach that the conservative substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha, while "nonconservative" substitutions with alanine or asparagine had no effect (see at least the Abstract). In the absence of specific guidance as to which region in the full length polypeptide would tolerate modifications, one skilled in the art would have to proceed with undue trial and error experimentation to screen through a vast number of polypeptides with multiple amino acid modifications to identify those having the functional activity of SEQ ID NO: 4.

Therefore, given the breadth of the claims; the lack of guidance as discussed supra; the unpredictability with regard to amino acid modifications; and the limited working examples, the claimed invention is not enabled throughout the broad scope.

See, *In re Wands* (*858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*. See also, *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991) where the court held that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a multitude of polypeptides having at least 80%, 85%, or 90% sequence identity to SEQ ID NO: 4 and retaining RuvB activity. In contrast, Applicant describes only SEQ ID NO: 4 and three other maize sequence. These are genus claims.

The claimed invention does not meet the written description requirement because Applicant has not described a representative number of polypeptides of the genus claimed. Nor that Applicant describes structural features common to all polypeptides having RuvB activity, which would allow one skilled in the art to predictably determine what will be the structure of the members of the genus. Applicant has not described a single variant having both the structural and functional properties as recited in the claims. Therefore, the disclosure of SEQ ID NO: 4 and few other maize sequences would not provide adequate written description for all polypeptides from any

sources having at least 80%, 85%, or 90% sequence identity to SEQ ID NO: 4. Therefore, given this lack of description of a representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that Applicant was in possession of the invention as broadly claimed at the time of filing.

See, the *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997) states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Therefore, weighing all factors above, the claimed invention does not meet the current written description requirements. See, also Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Remarks

Claims 1-5 are deemed free of the prior art of record because the prior art does not teach or reasonably suggest an isolated polypeptide having at least 80% sequence identity to SEQ ID NO: 4.

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 5 is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and After final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

08/20/04

Mai

Medina A. Ibrahim

MEDINA A. IBRAHIM
PATENT EXAMINER